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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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03/13/2002

FOLEY & LARDNER
3000 K STREET NW
SUITE 500
WASHINGTON, DC 20007

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/293,835

Applicant(s)

KENNEDY ET AL

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15-19 and 24-51 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17, 25, 26, 40 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 18-19, 24, 29³⁷, 39, 41-47, 49-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 16, 17, 25, 26, 40 and 48 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of species directed to fungus as the exogenous origin, skin as the tissue, onychomycosis as the disorder, and 5-aminolevulinic acid as the precursor of protoporphyrin IX is acknowledged.

Applicant's traversal that the Examiner has failed to establish that a search of the complete application would be an undue burden as required by MPEP 803, have been fully considered but are not persuasive, for the reasons set forth in the previous Office Action. Moreover, Applicant has failed to submit any evidence or identify such evidence now of record showing the species to be obvious variants or clearly admin on the record that this is the case. Accordingly, the requirement is proper.

Applicant is reminded that the requirement filed on December 13, 2001 was merely an election of species based on Markush format language wherein claims encompass multiple independent and patentably distinct inventions. Accordingly, in applications containing such claims, the Examiner may require a provisional election of species prior to examination on the merits. The provisional election will be given effect in the event that the Markush-type claim should be found not allowable. Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability (see MPEP § 803.02).

Subsequently, a search was conducted directed to the elected species wherein the exogenous origin, skin as the tissue, onychomycosis as the disorder, and 5-

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aminolevulinic acid as the precursor of protoporphyrin IX. Claims 1, 15, 18-19, 24, 29-39, 41-47, 49-51 are examined on the merits to the extent that they read on the elected species. Claims 16-17, 25-26, 40, 48 are withdrawn as they are not directed to the elected species.

Any rejection previously made that is not addressed in this Office Action is considered obviated in view of Applicant's arguments in Paper No. 9.

Priority

The effective priority date of the pending claims is considered to be the filing date of parent application 08/465,242 which is June 5, 1995 for the reasons set forth in the Office Action filed on June 12, 2000, Paper No. 8.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 15, 18-19, 24, 29-39, 41-47, 49-51 are rejected under the judicially created doctrine of double patenting over claims 1-12 of U. S. Patent No. 5,955,490

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since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed to methods of treating a skin condition comprising the same process steps as instantly claimed. Therefore, the instant claims are an obvious variant of the patented claims, because one of ordinary skill in the art would have had a reasonable expectation of success in practicing the same process steps in treating other infectious skin conditions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 15, 18-19, 24, ²⁵~~26~~-39, 41-47, 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter et al US Patent 5,705,518 in view of Levy et al US Patent 5,283,255.

The instant claims appear to be directed towards a method of treating skin disorders caused by an exogenous origin such as a fungus, comprising administering a precursor of protoporphyrin IX and further exposing the agent to light capable of photo activating protoporphyrin IX.

Richter teaches that protoporphyrin prodrugs such as 5-aminolevulinic acid can be used to treat skin infections such as papilloma virus (see col 5, lines 50-65). Richter

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teaches topical administration of the prodrug prior to employing photodynamic therapy (col 6, lines 1-20). Richter does not teach treatment of fungal skin conditions.

Levy teaches topical administration of protoporphyrin-IX derivatives for treatment of papilloma virus skin conditions (see col 34, lines 60-67; col 35, lines 1-67). Levy further indicates that such photodynamic treatment can be used to treat athlete's foot (see col 19, line 4). It is well known in the art that athlete's foot is caused by tinea pedis which leads to similar pathophysiological conditions such as onychomycosis.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to apply topical 5-aminolevulinic acid, as taught by Richter, to treat skin infections caused by tinea pedis or onychomycosis, because as taught by Levy, one of ordinary skill in the art would have had a reasonable expectation of success in treating skin conditions such as athlete's foot when employing photosensitizers such as hematoporphyrins.

Conclusion

No claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shikowitz US Patent 4,925,736 does not add any further teachings to the cited prior art, and Lurie US Patent 6,090,788 which is not a competent prior art as its effective priority date is after the effective priority date of the instant application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, JD can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.



Shahnam Sharareh, PharmD
Patent Examiner, Art Unit 1617

ss
March 11, 2002

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.